

# APPLICATION FOR UNITED STATES LETTERS PATENT

Title: "A Method of Using a Compound of Menthol and L-arginine as a Preparation for the Topical Delivery of a 5-phosphodiesterase Inhibitor for the Treatment of Female Sexual Dysfunction"


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signed 

Title: "A method of using a compound of menthol and L-arginine as a preparation for the topical delivery of a 5-phosphodiesterase inhibitor for the treatment of female sexual dysfunction"

### Field of the Invention

This invention relates to arrangements for the stimulation of females and more particularly to topical application of specialized stimulatory medicaments. This application is a continuation-in-part application of co-pending U.S. Patent Application serial no. 10/731,692 filed 9 December 2003 which is a divisional application of U.S. Patent Application serial no. 10/004,091, filed 23 Oct 2001, now U.S. Patent 6,702,733 issued 9 March 2004, which is a continuation of application no. 09/520,110, filed 7 March 2000, now U.S. Patent 6,322,493 which is a continuation-in-part of application no. 09/469,959 filed on 21 Dec 1999, which is a continuation-in-part of application no. 09/414,250, filed on 7 Oct 1999, now Patent no. 6,224,541 which is a continuation-in-part of application no. 09/340,227, filed on 1 July 1999, now U.S. Patent 6,179,775 each of which are incorporated herein by reference in their entirety.

## Background

The compound Sildenafil, known by the trademark Viagra®, is a 5-phosphodiesterase inhibitor that has proven to be a successful therapy for male erectile dysfunction. Sildenafil is an oral tablet. In a double-blind, placebo controlled clinical study of 583 women with diagnosed female sexual dysfunction; oral sildenafil was no more effective than a placebo. This study was conducted by Dr. Rosemary Basson.

Over several years, compounding pharmacists have attempted to develop a topical preparation of sildenafil to treat women with female sexual dysfunction, but this has proven less than effective because of the size of the Sildenafil molecule. Even when topically applied to the mucous membrane, which is more absorptive than hairy skin, the size of the sildenafil molecule requires the aid of a vehicle, or absorbing agent, to allow absorption of the sildenafil into the corpus cavernosa of the clitoris. The menthol component of the menthol/L-arginine combination acts as an immediate vasodilator of the vessels in the mucous membrane and functions as a lipophilic vehicle to facilitate the transport of the Sildenafil across the mucous membrane.

The L-arginine component of the menthol and L-arginine combination functions to induce the nitric oxide pathway as described in my U.S. Patent 6,702,733, incorporated by reference as stated hereinabove.

L-arginine is a semi-essential amino acid that is a component of a normal diet and stored in cellular tissues in minute amounts. By presenting L-arginine in abundant amounts directly to the corpus cavernosa, dietary intake of L-arginine is unnecessary for normal sexual responsiveness.

## Description of the Present Invention

The present invention relates to a manually applicable topical preparation comprising a compound of menthol or a menthol substitute, and L-arginine, and any 5-phosphodiesterase inhibitor as that topical compound. This manually applicable compound is to be manually applied directly to a woman's clitoris, for the treatment of female sexual dysfunction. Such 5-phosphodiesterase inhibitor in one preferred embodiment may preferably comprise less than 10% of that topical compound.

A first preferred embodiment of a Menthol substitute may be peppermint oil. A second preferred embodiment of a Menthol substitute may be cornmint oil. A third preferred embodiment of a Menthol substitute may be Eucalyptus oil. A fourth preferred embodiment of a Menthol substitute may be Citronella oil. A fifth preferred embodiment of a Menthol substitute may be Camphor oil. A sixth preferred embodiment of a Menthol substitute may be Cinnamon oil.

The invention thus comprises a manual application of a topical clitoral sensitizing combination consisting essentially of L-arginine and a cooling

agent comprised of Menthol and a 5-phosphodiesterase inhibitor, wherein the combination is applicable manually to the clitoris.

The cooling agent may in various preferred embodiments include peppermint oil. The cooling agent may include cornmint oil. The cooling agent may include Eucalyptus oil. The cooling agent may include Citronella oil. The cooling agent may include Camphor oil. The cooling agent may include Cinnamon oil. The cooling agent may essentially comprise peppermint oil. The cooling agent may essentially comprise cornmint oil. The cooling agent may essentially comprise Eucalyptus oil. The cooling agent may essentially comprise Citronella oil. The cooling agent may essentially comprise Camphor oil. The cooling agent essentially may comprise Cinnamon oil. The combination may contain less than 10% L-arginine. The combination may contain less than 10% menthol and the combination may contain less than 10% L-arginine and also the combination may contain less than 10% 5-phosphodiesterase inhibitor.